K083896

JUL - 2 2009

510(k) Summary

Destiny MAX

A. 510(k) Submitter Information:

Submitter's name:	Trinity Biotech
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Date of Preparation:	December, 15 2008

B. Device Information:

Trade Name:	Destiny MAX
Device Classification Name:	System, Multipurpose for in vitro coagulation studies, 21CFR864.5425, Product code JPA
Common Name:	Destiny MAX
C. Predicate Device:	AMAX Destiny™ Coagulation Analyzer (K021162)

Indications for Use
The Destiny Max Coagulation Analyzer is a multipurpose system for in vitro coagulation studies consisting of one automated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

Device Description

The Destiny Max instrument performs coagulation testing (clotting, chromogenic and immuno-turbidimetric) using human samples. The system is comprised of an instrument (Destiny Max Analyzer) that performs the tasks necessary to generate an assay result together with a Personal Computer (PC) that receives the user's requests and provides the results. The assays used with the Destiny Max are generally used for detection of clotting deficiencies or disorders and/or monitoring of anticoagulant therapy on various patient populations.

Predicate Device and Equivalence Information

The Destiny Max employs the same detection technologies previously employed in the predicate device with a new graphic user interface, cap piercing capability and enhanced through put. The Destiny Max system is substantially equivalent to the AMAX Destiny system in intended use and performance.

Device Technological Characteristics

Table 1 is a summary of the technological characteristics of the Destiny Max compared to the predicate device.

Table 1: Comparison of Technological Characteristics

Feature	AMAX Destiny	Destiny MAX
Integrated PC	Yes	No
Integrated Monitor	Yes	No
Touch screen	Yes	Yes
Instrument Drive and User Interface SW separated	No	Yes
Optical clotting	Yes	Yes
Minimum test volume in µL optical clotting	150	150
Mechanical clotting	Yes	Yes
Minimum test volume in µL mechanical clotting	75	75
Throughput PT	180	≈350
Throughput PT/PTT/FIB	110	≈300
Multishot sample	Yes	Yes
Multiple dispense reagent on appropriate reagents	Yes	Yes
Optical Wavelengths	405nm	340nm, 405nm, 635nm and 705nm
Cap piercing	No	Yes
QC scheduling	No	Yes
Result tracking to Lot#, operator, QC, calibration curve	No	Yes
Tracking of Operator to editing of assay definitions	Yes	Yes
Barcode ID of samples and reagents	Yes	Yes

Device Performance Characteristics – Method Comparison
Table 2 describes the performance of the Destiny Max system when compared to the predicate at 3 sites using a variety of clinical samples.

Assay	Site	N	Slope	Intercept	R
TriniCLOT PT HTF Optical Mode Seconds	1	77	1.04	-2.00	1.00
TriniCLOT PT HTF Optical Mode Seconds	2	42	1.00	-1.28	0.99
TriniCLOT PT HTF Optical Mode Seconds	3	85	1.23	-3.71	0.99
TriniCLOT PT HTF Mechanical Mode Seconds	1	80	1.02	-1.37	1.00
TriniCLOT PT HTF Mechanical Mode Seconds	2	51	1.02	-1.66	1.00
TriniCLOT PT HTF Mechanical Mode Seconds	3	86	1.21	-3.01	1.00

Assay	Site	N	Slope	Intercept	R
TriniCLOT Excel S Optical Mode Seconds	1	77	1.03	-1.61	1.00
TriniCLOT Excel S Optical Mode Seconds	2	43	0.99	-1.36	1.00
TriniCLOT Excel S Optical Mode Seconds	3	75	1.01	-0.05	1.00
TriniCLOT Excel S Mechanical Mode Seconds	1	78	1.09	-2.08	1.00
TriniCLOT Excel S Mechanical Mode Seconds	2	49	1.04	-1.29	1.00
TriniCLOT Excel S Mechanical Mode Seconds	3	78	1.13	-1.43	1.00
TriniCLOT APTT S Optical Mode Seconds	1	63	0.97	-1.82	0.99
TriniCLOT APTT S Optical Mode Seconds	2	49	0.87	1.57	0.93
TriniCLOT APTT S Optical Mode Seconds	3	80	1.03	-3.11	0.99
TriniCLOT APTT S Mechanical Mode Seconds	1	67	0.91	2.65	0.99
TriniCLOT APTT S Mechanical Mode Seconds	2	57	1.05	-2.08	0.97
TriniCLOT APTT S Mechanical Mode Seconds	3	86	1.01	-0.27	0.98
TriniCLOT Thrombin Time Mechanical Mode Seconds	1	50	1.21	-3.35	0.97
TriniCLOT Thrombin Time Mechanical Mode Seconds	2	19	0.89	0.91	0.96
TriniCLOT Thrombin Time Mechanical Mode Seconds	3	73	1.04	-0.37	0.99
TriniCLOT Fibrinogen Optical Mode mg/dL	1	80	0.90	15.56	1.00
TriniCLOT Fibrinogen Optical Mode mg/dL	2	69	1.02	-5.45	0.98
TriniCLOT Fibrinogen Optical Mode mg/dL	3	68	0.73	71.70	0.95
TriniCLOT Fibrinogen Mechanical Mode mg/dL	1	80	0.86	44.28	0.99
TriniCLOT Fibrinogen Mechanical Mode mg/dL	2	65	1.10	-21.04	0.97
TriniCLOT Fibrinogen Mechanical Mode mg/dL	3	60	0.91	49.84	0.94
TriniCLOT FVII Optical Mode %	1	77	0.94	0.30	0.98
TriniCLOT FVII Optical Mode %	2	81	0.99	-1.65	0.98
TriniCLOT FVII Optical Mode %	3	57	0.78	8.56	0.98
TriniCLOT FVII Mechanical Mode %	1	77	0.98	3.91	0.96
TriniCLOT FVII Mechanical Mode %	2	82	0.89	10.35	0.96
TriniCLOT FVII Mechanical Mode %	3	58	0.82	6.87	0.96
TriniCLOT FIX Optical Mode %	1	117	0.84	0.92	0.88
TriniCLOT FIX Optical Mode %	2	76	1.01	-1.43	0.97
TriniCLOT FIX Optical Mode %	3	60	1.06	-6.17	0.95
TriniCLOT FIX Mechanical Mode %	1	117	0.96	3.21	0.90
TriniCLOT FIX Mechanical Mode %	2	77	0.95	1.46	0.96
TriniCLOT FIX Mechanical Mode %	3	60	0.87	2.60	0.97
TriniCHROM Antithrombin IIa %	1	80	0.98	7.87	0.99
TriniCHROM Antithrombin IIa %	2	77	0.84	4.52	0.97
TriniCHROM Antithrombin IIa %	3	80	0.95	13.62	0.99
TriniLIA D-Dimer ng/mL	1	76	0.88	182.84	0.99
TriniLIA D-Dimer ng/mL	2	68	1.28	-184.08	0.99
TriniLIA D-Dimer ng/mL	3	79	1.14	-435.84	0.98

Device Performance Characteristics - Linearity
Table 3 describes the linearity data generated for calibrated assays on the Destiny Max system.

Assay	Range %	R
TriniCLOT Fibrinogen Optical Mode	64 - 1400	0.993
TriniCLOT Fibrinogen Mechanical Mode	62 - 844	1.000
TriniCLOT Factor VII Optical Mode	1 - 112	0.998
TriniCLOT Factor VII Mechanical Mode	2 - 110	0.998
TriniCLOT Factor IX Optical Mode	0 - 230	0.996
TriniCLOT Factor IX Mechanical Mode	0 - 104	0.996
TriniCHROM Antithrombin Chromogenic Mode	0 -150	0.998
TriniLIA D-Dimer Immunoturbidometric Mode	70 - 13911	0.996

Device Performance Characteristics - Precision
Tables 4 to 12 describe the precision data generated at 3 sites

Table 4a: Level 1 Precision Data TriniCLOT PT HTF

Level 1	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	57	12.3	0.32	2.6	12.3	0.42	3.4	57	12.8	0.31	2.4	12.8	0.41	3.2
Site 2	56	12.6	0.29	2.3	12.6	0.58	4.6	60	12.8	0.28	2.2	12.8	0.5	3.9
Site 3	60	12.5	0.26	2.1	12.5	0.28	2.3	58	12.5	0.15	1.2	12.5	0.27	2.2

Table 4b: Level 2 Precision Data TriniCLOT PT HTF

Level 2	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	56	20.7	0.46	2.2	20.7	0.55	2.6	56	21.2	0.52	2.4	21.2	0.58	2.7
Site 2	56	21.2	0.41	1.9	21.2	0.57	2.7	59	21.5	0.39	1.8	21.5	0.40	1.9
Site 3	59	21.1	0.34	1.6	21.1	0.42	2.0	57	21.0	0.2	0.9	21.0	0.38	1.8

Table 4c: Level 3 Precision Data TriniCLOT PT HTF

Level 3	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	53	34.8	0.57	1.6	34.8	0.56	1.6	55	34.7	0.51	1.5	35.7	0.68	1.9
Site 2	59	35.5	0.54	1.5	35.5	0.81	2.3	60	36.1	0.86	2.4	36.1	1.05	2.9
Site 3	60	35.1	0.47	1.3	35.1	0.7	2.0	60	35.4	0.39	1.1	35.4	0.58	1.7

Table 5a: Level 1 Precision Data TriniCLOT PT Excel S

Level 1	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	54	13.6	0.24	1.7	13.6	0.25	1.8	57	14.2	0.21	1.5	14.2	0.26	1.8
Site 2	54	13.8	0.23	1.6	13.8	0.43	3.1	59	14.4	0.22	1.5	14.4	0.47	3.3
Site 3	60	13.4	0.26	1.9	13.4	0.29	2.2	59	14.0	0.24	1.7	14.0	0.28	2.0

Table 5b: Level 2 Precision Data TriniCLOT PT Excel S

Level 2	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	56	23.9	0.36	1.5	23.9	0.61	2.6	57	25.4	0.46	1.8	25.4	0.75	3.0
Site 2	45	24.8	0.5	2.0	24.8	1.04	4.3	59	26.3	0.31	1.2	26.3	1.08	4.1
Site 3	59	23.2	0.40	1.7	23.2	0.62	2.7	58	25.1	0.52	2.1	25.1	0.76	3.0

Table 5c: Level 3 Precision Data TriniCLOT PT Excel S

Level 3	Mode: Clotting														
	Optical							Mechanical							
	Within Run				Total			Within Run				Total			
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV	
Site 1	57	42.8	0.68	1.6	42.8	1.60	3.8	57	45.9	0.79	1.7	45.9	1.72	3.8	
Site 2	57	42.8	0.69	1.6	42.8	2.28	5.3	60	47.4	0.95	2.0	47.4	2.62	5.5	
Site 3	59	39.9	0.44	1.1	39.9	1.02	2.5	60	43.5	1.04	2.4	43.5	1.76	4.1	

Table 6a: Level 1 Precision Data TriniCLOT APTT S

Level 1	Mode: Clotting														
	Optical							Mechanical							
	Within Run				Total			Within Run				Total			
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV	
Site 1	57	30.9	0.21	0.7	30.9	0.4	1.3	57	32.4	0.73	2.3	32.4	0.97	3.0	
Site 2	59	30.7	0.29	0.9	30.6	0.59	1.9	60	33.3	1.12	3.4	33.3	1.19	3.6	
Site 3	59	30.6	0.21	0.7	30.6	0.35	1.1	58	32.4	0.66	2.0	32.4	0.82	2.5	

Table 6b: Level 2 Precision Data TriniCLOT APTT S

Level 2	Mode: Clotting														
	Optical							Mechanical							
	Within Run				Total			Within Run				Total			
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV	
Site 1	57	65.3	0.59	0.9	65.3	1.00	1.5	56	69.1	1.13	1.6	69.1	1.64	2.4	
Site 2	53	63.0	0.75	1.2	63.0	1.81	2.9	52	69.0	2.24	3.2	69.0	2.56	3.7	
Site 3	57	61.1	0.37	0.6	61.1	1.81	3.0	57	66.1	1.21	1.8	66.1	1.71	2.6	

Table 6c: Level 3 Precision Data TriniCLOT APTT S

Level 3	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	57	94.8	1.08	1.1	94.8	1.63	1.7	56	101.0	2.95	2.9	101.0	4.12	4.1
Site 2	59	91.0	1.59	1.7	91.0	2.18	2.4	58	96.7	3.80	3.9	96.7	9.20	9.5
Site 3	59	87.0	0.69	0.8	87.0	2.55	2.9	58	94.7	1.92	2.0	94.7	2.89	3.1

Table 7a and Table 7b: Level 1 and Level 2 Precision Data TriniCLOT Thrombin Time

Level 1	Mode: Clotting						
	Optical						
	Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	59	15.8	0.41	2.6	15.8	0.49	3.1
Site 2	47	15.1	0.16	1.1	15.1	2.5	1.7
Site 3	56	15.0	0.38	2.5	15.0	0.49	3.3

Level 2	Mode: Clotting						
	Optical						
	Within Run				Total		
	N	Sec	SD	%CV	Sec	SD	%CV
Site 1	60	18.8	0.27	1.5	18.8	0.40	2.1
Site 2	59	18.7	0.24	1.3	18.7	0.45	2.4
Site 3	54	18.4	0.30	1.6	18.4	0.32	1.8

Table 8a: Level 1 Precision Data TriniCLOT Fibrinogen

Level 1	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	mg/dL	SD	%CV	mg/dL	SD	%CV	N	mg/dL	SD	%CV	mg/dL	SD	%CV
Site 1	60	339.4	8.18	2.4	339.4	12.26	3.6	60	295.3	5.54	1.9	295.3	6.39	2.2
Site 2	54	311.9	5.89	1.9	311.9	11.4	3.7	47	343.0	6.77	2.0	343.0	10.14	3.0
Site 3	60	288.1	4.63	1.6	288.1	7.14	2.5	59	336.9	7.37	2.2	336.9	9.27	2.8

Table 8b: Level 2 Precision Data TriniCLOT Fibrinogen

Level 2	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	mg/dL	SD	%CV	mg/dL	SD	%CV	N	mg/dL	SD	%CV	mg/dL	SD	%CV
Site 1	60	129.1	4.35	3.5	129.1	5.34	4.4	60	111.4	5.52	5.0	111.4	6.99	6.3
Site 2	53	124.2	6.97	5.6	124.2	9.76	7.9	51	132.1	2.11	1.6	132.1	6.51	4.9
Site 3	59	110.1	3.78	3.4	110.1	4.47	4.1	59	126.3	6.25	4.9	126.3	8.76	6.9

Table 9a: Level 1 Precision Data TriniCLOT FVII

Level 1	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	%	SD	%CV	%	SD	%CV	N	%	SD	%CV	%	SD	%CV
Site 1	60	100.8	10.31	10.2	100.8	12.93	12.8	60	105.1	11.72	11.1	105.1	14.83	14.1
Site 2	60	113.9	9.06	8.0	113.9	10.95	9.6	60	128.2	10.20	8.0	128.2	10.86	8.5
Site 3	59	115.3	10.15	8.8	115.3	10.15	8.8	60	103.8	7.05	6.8	103.8	7.45	7.2

Table 9b: Level 2 Precision Data TriniCLOT FVII

Level 2	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	%	SD	%CV	%	SD	%CV	N	%	SD	%CV	%	SD	%CV
Site 1	60	20.3	1.35	6.6	20.3	1.85	9.1	60	21.4	1.56	7.3	21.4	2.52	11.7
Site 2	60	20.6	1.36	6.6	20.6	1.62	7.9	60	20.5	1.26	6.1	20.5	1.49	7.3
Site 3	58	22.3	1.16	5.2	22.3	1.3	5.8	60	22.7	1.02	4.5	22.7	1.08	4.7

Table 9c: Level 3 Precision Data TriniCLOT FVII

Level 3	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	%	SD	%CV	%	SD	%CV	N	%	SD	%CV	%	SD	%CV
Site 1	60	10.8	0.86	8.0	10.8	1.02	9.4	60	12.2	0.64	5.3	12.2	0.78	6.4
Site 2	60	11.5	0.68	5.9	11.5	0.92	8.1	60	13.0	1.30	10.0	13.0	1.93	14.9
Site 3	58	13.0	1.09	8.4	13.0	1.33	10.3	60	12.3	0.68	5.5	12.3	0.69	5.6

Table 10a: Level 1 Precision Data TriniCLOT FIX

Level 1	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	%	SD	%CV	%	SD	%CV	N	%	SD	%CV	%	SD	%CV
Site 2	60	113.1	8.41	7.4	113.1	17.43	15.4	59	107.3	3.94	3.7	107.3	11.60	10.8
Site 3	60	89.7	5.02	5.6	89.7	6.68	7.4	58	91.4	7.33	8.0	91.4	7.51	8.2

Table 10b: Level 2 Precision Data TriniCLOT FIX

Level 2	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	%	SD	%CV	%	SD	%CV	N	%	SD	%CV	%	SD	%CV
Site 2	58	16.8	1.35	8.0	16.8	2.49	14.9	60	19.0	0.75	4.0	19.0	3.97	20.9
Site 3	58	18.6	1.11	5.9	18.6	2.47	13.2	58	17.2	1.41	8.2	17.2	2.28	13.3

Table 10c: Level 3 Precision Data TriniCLOT FIX

Level 3	Mode: Clotting													
	Optical							Mechanical						
	Within Run				Total			Within Run				Total		
	N	%	SD	%CV	%	SD	%CV	N	%	SD	%CV	%	SD	%CV
Site 2	60	8.1	0.91	11.3	8.1	1.14	14.1	60	9.5	0.81	8.5	9.5	2.18	23.0
Site 3	57	9.9	1.64	16.6	9.9	1.99	20.2	56	9.3	1.15	12.4	9.3	2.25	24.2

Table 11: Level 1 and Level 2 Precision Data TriniCHROM Antithrombin

Level 1	Mode: Chromogenic							Level 2	Mode: Chromogenic						
	Optical								Optical						
	Within Run				Total				Within Run				Total		
	N	%	SD	%CV	Sec	SD	%CV		N	%	SD	%CV	Sec	SD	%CV
Site 1	56	129.8	6.57	5.1	129.8	6.65	5.1	Site 1	60	49.9	2.36	4.7	49.9	2.66	5.3
Site 2	58	121.1	5.78	4.8	121.1	8.08	6.7	Site 2	60	44.6	1.50	3.4	44.6	2.46	5.5
Site 3	48	125.0	3.38	2.7	125.0	7.95	6.4	Site 3	47	45.9	2.56	5.6	45.9	4.62	10.1

Table 12a: Level 1 Precision Data TriniLIA D-Dimer

Level 1	Mode: Immunoturbidometric						
	Optical						
	Within Run				Total		
	N	ng/mL	SD	%CV	Sec	SD	%CV
Site 1	59	310.1	37.29	12.0	310.1	55.4	17.9
Site 2	60	348.7	49.08	14.1	348.7	71.13	20.4
Site 3	60	333.7	33.04	9.9	333.7	45.20	13.5

Table 12b: Level 1 Precision Data TriniLIA D-Dimer

Level 2	Mode: Immunoturbidometric						
	Optical						
	Within Run				Total		
	N	ng/mL	SD	%CV	Sec	SD	%CV
Site 1	58	1657.7	93.67	5.7	1657.7	120.08	7.2
Site 2	59	1618.8	67.57	4.2	1618.8	67.54	4.2
Site 3	60	1753.1	55.1	3.1	1753.1	86.85	5.0

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Trinity Biotech
c/o Ms. Bonnie B. DeJoy
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Trinity Biotech, USA
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JUN 02 2010

Re: k083896
Trade/Device Name: Destiny MAX
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: June 15, 2009
Received: June 17, 2009

Dear Ms. DeJoy::

This letter corrects our substantially equivalent letter of July 2, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical

device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K083896

Device Name: Destiny MAX

Indication for Use:

The Destiny Max Coagulation Analyzer is a multipurpose system for in vitro coagulation studies consisting of one automated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

Prescription Use √ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083896

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